

EXHIBIT 33

3M Health Care Business Group
 3M Center Bldg. 275-05-W-06
 St. Paul, MN 55144-1000
 651 733 1110

December 1, 2016



Via E-Mail and Overnight Delivery

Dr. Michael Dutcher
 District Director
 Food and Drug Administration, Minneapolis District Office
 250 Marquette Avenue South, Suite 600
 Minneapolis, MN 55401

Dear Dr. Dutcher:

I am writing to clarify a statement made by the investigator in FDA's Establishment Inspection Report (EIR) following an inspection of Arizant between November 30, 2009 and January 6, 2010. (Arizant was the company manufacturing the Bair Hugger system at the time. 3M acquired the Bair Hugger product line in October 2010.)

We recently reviewed FDA's EIR from that inspection investigating a trade complaint regarding potential microbial contamination. In that inspection, FDA examined complaints from January 2006 through the time of the inspection, and found none that revealed any reports of microbial air contamination. FDA also reviewed several independently conducted studies which conclude that forced air warming systems do not increase bacterial contamination in the operating room. FDA found no evidence to support the complaint allegations.

We notice, however, that the EIR, p. 4, describes the Bair Hugger devices as having a "0.2 μ m HEPA filter." The Bair Hugger units have never had a "HEPA" filter as that term is defined by industry standards. It is accurate to say that the Bair Hugger units have filters that perform consistently with the American Society of Heating Refrigeration and Air Conditioning Engineers (ASHRAE) standards for operating room ventilation systems (MERV rating 14-16). 3M reviewed the documents Arizant provided to the FDA during the 2009 – 2010 inspection and at prior inspections, and did not find documents indicating that the Bair Hugger devices have a HEPA filter. Records provided during the inspection, within product literature and documenting internal product specifications describe the filter as "0.2 μ m" with no "HEPA" designation.

Your correction of the record is appreciated. Please let me know if you have any questions regarding this request.

Sincerely,

Suzanne M. Danielson, Director
 Regulatory Affairs and Quality Compliance
 3M Health Care Business Group
 3M Center, Bldg. 275-05W-06 Room 5B09
 Saint Paul, MN 55144-1000

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